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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,204	05/04/2007	Simon Bates	09013.0010	5565

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EXAMINER

KILPATRICK, BRYAN T

ART UNIT	PAPER NUMBER
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1772

MAIL DATE	DELIVERY MODE
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10/25/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,204	Applicant(s) BATES ET AL.	
	Examiner BRYAN KILPATRICK	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-16 is/are pending in the application.
- 5a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 15 and 16 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The arguments/remarks filed on 13 August 2011 have been entered and fully considered.
2. Instant claims 15-16 are pending currently, instant claims 1-14 have been cancelled previously.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 February 2011 has been entered.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Terminal Disclaimer

The terminal disclaimer filed on 05 August 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date

of U.S. Patent 7,372,941(issued from application no. 10/635,113) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0123057 (LEMMO et al.) in view of "Structure by diffraction of X-rays of liquid gallium between +50 and 110°C," *Physica Status Solidi A*, 23(1); 135-145; 1974 (BIZID et al.).

In regards to instant claims 15-16, LEMMO et al. discloses a method of screening an array of samples and determining if any share spectral features, similar to comparing diffraction patterns (paragraphs [0017]-[0023]), as well as the use of X-ray diffraction analysis (paragraph [0141]). LEMMO et al. discloses an example of comparing different forms of a sample of flufenamic acid 176 and theophylline 178 samples (Fig. 19A-B and paragraph [0209]). LEMMO et al. discloses employing a binning system to detect similarities in properties of a plurality of samples by observing their binning behavior wherein a plurality of samples are examined with a device for generating a corresponding spectrum, spectral peaks or other features are next identified to obtain a binary fingerprint, and then the spectra are compared pairwise in accordance with a metric to generate a similarity score; however, other comparisons that use more than two spectra concurrently are also acceptable, although possibly complex (paragraph [0162]). LEMMO et al. discloses that their invention is directed to methods and systems for the generation, synthesis, and/or identification of various forms of a compound or composition such as amorphous forms (paragraph [0009]); and discloses differentiating between crystalline versus amorphous solid forms (paragraphs

[0037] and [0128], and Fig. 11). LEMMO et al. further discloses that compounds of interest for analysis include pharmaceuticals (paragraph [0076]).

LEMMO et al. does not expressly disclose the use of pair distribution function - PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample (English Abstract, p. 135). Since both LEMMO et al. and BIZID et al. employ X-ray diffraction for the analysis of sample structure, it would have been obvious to one of ordinary skill in the art to employ PDF with X-ray diffraction analysis for the purpose of comparing forms of a sample such as liquid and crystalline forms (English Abstract of BIZID et al.).

Response to Arguments

Applicant's arguments/remarks filed 13 August 2011 have been fully considered but they are not persuasive.

Applicant states on p. 3-6 of the remarks filed on 13 August 2011 that "Neither Bizid nor Lemmo, nor the combination thereof, render the claimed method obvious, and further because there would have been no motivation to combine the teachings of Lemmo and Bizid..." Applicant further states on page 6 that "... one of skill in the art would consider Bizid as **teaching away from** using the PDF to find residual crystallinity in any other substance such as an amorphous or otherwise disordered pharmaceutical." and that "Lemmo adds nothing to the analysis. There is no mention or suggestion of the PDF or radial distribution function, and references to other techniques therein are

irrelevant to the claims at issue which are limited to the PDF technique. As such, one of skill in the art would not have been motivated to modify the methods of Lemmo to incorporate the PDF of Bizid, in such a way as to arrive at the presently claimed invention.”

The Examiner respectfully disagrees. As previously stated above, LEMMO et al. discloses a method of screening an array of samples and determining if any share spectral features, similar to comparing diffraction patterns (paragraphs [0017]-[0023]), as well as the use of X-ray diffraction analysis (paragraph [0141]). LEMMO et al. discloses that their invention is directed to methods and systems for the generation, synthesis, and/or identification of various forms of a compound or composition such as amorphous forms (paragraph [0009]); and discloses differentiating between crystalline versus amorphous solid forms (paragraphs [0037] and [0128], and Fig. 11). LEMMO et al. further discloses that compounds of interest for analysis include pharmaceuticals (paragraph [0076]). LEMMO et al. does not expressly disclose the use of pair distribution function - PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample (English Abstract, p. 135). Since LEMMO et al. discloses comparing and identifying various forms of pharmaceutical compounds or compositions using X-ray diffraction analysis and since BIZID et al. discloses that PDF is employed with X-ray diffraction for comparing physical characteristics of samples, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ PDF for comparing different forms (i.e. crystalline, amorphous solid forms, or liquid

form) of a material, as disclosed by the combination of LEMMO et al. and BIZID et al. in the rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571)272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. K./
Examiner, Art Unit 1772

/SAM P SIEFKE/
Primary Examiner, Art Unit 1772